FEB 2 4 2012

510(k) Summary
(As required by 21 CFR 807.92(a))

Date Prepared: September 19, 2011

A. Submitter Information

Sol-Millennium Medical, Inc.
5415 Sugarloaf Parkway
Suite 2203
Lawrenceville, GA 30043

Phone Number: 404-973-2200
Contact: Karen Dunlap
President

Trade Name: Sol-M Exchangeable Needles

B. Device Information

Trade/Proprietary Name:	Sol-M Exchangeable Needles
Common name of device:	Syringe Cannula
Classification Name:	Needle, Hypodermic, Single Lumen
Product Code:	80 FMI
Regulatory Class:	II
Classification Number:	880.5570
Reason for 510(k):	New Device

C. Predicate Device: DuoPross Needles

Predicate 510(k) #: K052445

Predicate product code: FMI

D. Device Description

The Sol-M Exchangeable Needles are a sterile, single use, standard hypodermic needle. The device is available in 16 to 31 gauge and in lengths from 5/16" to 1-1/2". In addition, the needle tip is available in a regular or short bevel.

Each needle device consists of a stainless steel cannula sealed with epoxy glue into a polypropylene hub. The assembly has a protective polypropylene needle cap/shield.

The Sol-M Exchangeable Needles are sterilized by Ethylene Oxide Gas and supplied sterile in blister pack. One hundred blister packs are packaged in a chipboard box. Each Blister pack and chipboard box is labeled with the contents and the appropriate information per the FDA's Quality System Regulation and Labeling requirements.

E. Statement of Indications for Use

The Sol-M Exchangeable Needles are sterile hypodermic needles intended to inject fluids into, or withdraw fluids from, parts of the body below the surface of the skin.

F. Comparison of Required Technological Characteristics:

Information was submitted to demonstrate that there are no significant differences in technological characteristics between the Sol-M Exchangeable Needles and the DuoPross Needles. This included:

1. Label Review
    a. Both devices had similar device descriptions
    b. Both devices were labeled as EO Sterilized, non pyrogenic, non toxic, single use, latex free and with a five year shelf life.
2. Intended Use Comparison
    a. The intended use for both devices is the same.
3. Material Comparison
    a. Both devices are fabricated from the same materials.
4. Physical, mechanical and biological specifications
    a. A comparison of physical, mechanical and biological specifications showed that the Sol-M Exchangeable Needles are substantially equivalent to the predicate device.

G. Summary and Conclusion of Nonclinical and Clinical Tests:

The Sol-M Exchangeable Needles met the appropriate requirements contained in the following standards:

1. ISO 7864, Sterile Hypodermic Needles for Single Use;

2. ISO 594, Conical Fittings with a 6% (Luer) Taper for Syringes, Needles, and Certain Other Medical Equipment;

3. ISO 9626, Stainless Steel Needle Tubing for Manufacture of Medical Devices;

4. ISO 6009, Hypodermic Needles for Single Use - Colour Coding for Identification;

H. Discussion of Clinical Tests:

None submitted

I. Conclusions Demonstrating Safety, Effectiveness and Performance:

The device has been tested and found to meet all product specifications and requirements. Accelerated aging was used to verify the performance of the product over the life of the device.

Instructions for Use detail how to use the devices and the conditions of use. Product labeling clearly shows that the device is for single patient use only.

The Sol-M Exchangeable Needles have been found to be safe and effective for their intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Sol-Millennium Medical, Inc.
C/O Mr. Jim Barley
President
Abrimed Consulting
33822 Malaga Drive
Dana Point, California 92629

FEB 2 4 2012

Re: K112777
Trade/Device Name: Sol-M Exchangeable Needles
Regulation Number: 21 CFR 880.5570
Regulation Name: Hypodermic Single Lumen Needle
Regulatory Class: II
Product Code: FMI
Dated: December 27, 2011
Received: February 22, 2012

Dear Mr. Barley:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K112777

Indications For Use

510(k) Number (if known):_____

Device Name: Sol-M Exchangeable Needles

Indications For Use:

The Sol-M Exchangeable Needles are sterile hypodermic needles intended to inject fluids into, or withdraw fluids from, parts of the body below the surface of the skin.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

for RZC Feb 22, 2012
(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K112777